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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,143	01/16/2001	Muraleedharan G. Nair	MSU 4.1-541	4327

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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/761,143	NAIR ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/9/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,15-18,27-30 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,15-18,27-30 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-6, 15-18, 27-30 and 34 are pending in the application and were examined on their merits.

It is noted that some claims were inadvertently omitted from the previous Office Action. Further, a new Inventor search requires additional Double Patenting rejections (see *infra*). For these reasons, this action is Non-final.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,818,234, in view of Gryglewski et al. (1987) in view of Hellburg et al. (US 5,691,360 A).

Claims 1-15 of '234 teach a method for alleviating or reducing pain an a mammal by administration of anthocyanins. Although the claims do not specifically state wherein cyclooxygenase is inhibited, this is the only necessary conclusion based upon the teachings of the '234 specification. It is drawn from the claims of '234 that the anthocyanins are extracted from the other endogenous ingredients of the cherry and therefore it is deemed that the extract does not contain natural acids. The claims of '234 do not specifically teach the incorporation of isolated cyanidin or a food-grade acid.

Gryglewski et al. (1987) studied the anti-inflammatory mechanism of 3-cyanidol (cyanidin) *inter alia* and discovered that cyanidin inhibits cyclooxygenase (see entire reference, especially pp. 318 – 319 and Table 10). It is noted that cyclooxygenase is a synonym for prostaglandin H synthase/synthetase.

Hellburg et al. (US 5,691,360 A) taught that:

> The antioxidant activity of the phenolic compounds is enhanced by stabilizing the phenoxyl flee radical or by facilitating the transfer of the free radical to other components of the detoxification mechanism, such as GSH

> or vitamin C. Alkyl substituents stabilize the phenoxyl free radical by electron donation and the stearic bulk of ortho substituents reduces the propensity of the phenoxyl radical to participate in free radical chain reactions (col. 6, line 66-col.7, line 6).

One of ordinary skill in the art would have been motivated to add a food grade acid such as vitamin c (ascorbic acid) to a combination of anthocyanin and cyanidin in order to stabilize the antioxidant activities of anthocyanin and cyanidin. One of ordinary skill in the art would have had a reasonable expectation that vitamin c, being a strong antioxidant and also being know to stabilize phenolic compounds, would have been advantageous to add to a composition comprising the phenolics anthocyanin and cyanidin.

Therefore, it would have been obvious to administer cyanidin along with anthocyanins a cyanidin-3-glucoside which yield the aglycone structures of cyanidin because it was already known in the art that cyanidin inhibited cyclooxygenase and was therefore an inhibitor of inflammation. One of ordinary skill in the art would have had a reasonable expectation that the combination of cyanidin and anthocyanin would have provided for a combined effect of treating inflammation.

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,194,469 , in view of Gryglewski et al. (1987) in view of Hellburg et al. (US 5,691,360 A).

Claims 1-8 of '469 teach a method for inhibiting cyclooxygenase or prostaglandin H synthase via administration of specific anthocyanins from a cherry. It is drawn from the claims that the anthocyanins are extracted from the other endogenous ingredients of the cherry and therefore it is deemed that the extract does not contain natural acids. The claims do not specifically teach the incorporation of isolated cyanidin or a food-grade acid.

Gryglewski et al. (1987) studied the anti-inflammatory mechanism of 3-cyanidol (cyanidin) *inter alia* and discovered that cyanidin inhibits cyclooxygenase (see entire reference, especially pp. 318 – 319 and Table 10). It is noted that cyclooxygenase is a synonym for prostaglandin H synthase/synthetase.

Hellburg et al. (US 5,691,360 A) taught that:

> The antioxidant activity of the phenolic compounds is enhanced by stabilizing the phenoxyl flee radical or by facilitating the transfer of the free radical to other components of the detoxification mechanism, such as GSH or vitamin C. Alkyl substituents stabilize the phenoxyl free radical by electron donation and the stearic bulk of ortho substituents reduces the propensity of the phenoxyl radical to participate in free radical chain reactions (col. 6, line 66-col.7, line 6).

One of ordinary skill in the art would have been motivated to add a food grade acid such as vitamin c (ascorbic acid) to a combination of anthocyanin and cyanidin in order to stabilize the antioxidant activities of anthocyanin and cyanidin. One of ordinary skill in the art would have had a reasonable expectation that vitamin c, being a strong

antioxidant and also being know to stabilize phenolic compounds, would have been advantageous to add to a composition comprising the phenolics anthocyanin and cyanidin.

Therefore, it would have been obvious to administer cyanidin along with anthocyanins a cyanidin-3-glucoside which yield the aglycone structures of cyanidin because it was already known in the art that cyanidin inhibited cyclooxygenase and was therefore an inhibitor of inflammation. One of ordinary skill in the art would have had a reasonable expectation that the combination of cyanidin and anthocyanin would have provided for a combined effect of treating inflammation.

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,676,978 in view of Gryglewski et al. (1987) in view of Hellburg et al. (US 5,691,360 A).

Claims 1-8 of '978 teach a method for inhibiting inflammation via administration of specific anthocyanins from a cherry. Although the claims do not specifically state wherein cyclooxygenase is inhibited, this is the only necessary conclusion based upon the teachings of the '978 specification. The claims specifically state that the extract is free of organic acids from the cherry. The claims do not specifically teach the incorporation of isolated cyanidin or a food-grade acid.

Gryglewski et al. (1987) studied the anti-inflammatory mechanism of 3-cyanidol (cyanidin) *inter alia* and discovered that cyanidin inhibits cyclooxygenase (see entire reference, especially pp. 318 – 319 and Table 10). It is noted that cyclooxygenase is a synonym for prostaglandin H synthase/synthetase.

Hellburg et al. (US 5,691,360 A) taught that:

> The antioxidant activity of the phenolic compounds is enhanced by stabilizing the phenoxyl flee radical or by facilitating the transfer of the free radical to other components of the detoxification mechanism, such as GSH or vitamin C. Alkyl substituents stabilize the phenoxyl free radical by electron donation and the stearic bulk of ortho substituents reduces the propensity of the phenoxyl radical to participate in free radical chain reactions (col. 6, line 66-col.7, line 6).

One of ordinary skill in the art would have been motivated to add a food grade acid such as vitamin c (ascorbic acid) to a combination of anthocyanin and cyanidin in order to stabilize the antioxidant activities of anthocyanin and cyanidin. One of ordinary skill in the art would have had a reasonable expectation that vitamin c, being a strong antioxidant and also being know to stabilize phenolic compounds, would have been advantageous to add to a composition comprising the phenolics anthocyanin and cyanidin.

Therefore, it would have been obvious to administer cyanidin along with anthocyanins a cyanidin-3-glucoside which yield the aglycone structures of cyanidin because it was already known in the art that cyanidin inhibited cyclooxygenase and was

therefore an inhibitor of inflammation. One of ordinary skill in the art would have had a reasonable expectation that the combination of cyanidin and anthocyanin would have provided for a combined effect of treating inflammation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-18 are is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites 'the cherries'. This phrase lacks antecedent basis in that claim 1 does not recite 'cherries'. Because claims 16-18 depend upon claim 15, claims 16-18 necessarily possess all of the limitations of claim 15. Because claims 16-18 do not overcome the deficiency of claim 15 as rejected under this statute, claims 16-18 are properly rejected under this statute.

Claim Rejections - 35 USC § 103

Claims 1, 3-6, 27-30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gryglewski et al. (1987) in view of Lietti et al. (GB 1,589,294). in view of Hellburg et al. (US 5,691,360 A).

The teachings of Gryglewski et al. and Lietti et al. were discussed keenly in the previous Office Action. Neither reference specifically taught the incorporation of a food grade acid to a cyanidin or anthocyanin.

Hellburg et al. (US 5,691,360 A) taught that:

> The antioxidant activity of the phenolic compounds is enhanced by stabilizing the phenoxyl flee radical or by facilitating the transfer of the free radical to other components of the detoxification mechanism, such as GSH or vitamin C. Alkyl substituents stabilize the phenoxyl free radical by electron donation and the stearic bulk of ortho substituents reduces the propensity of the phenoxyl radical to participate in free radical chain reactions (col. 6, line 66-col.7, line 6).

One of ordinary skill in the art would have been motivated to add a food grade acid such as vitamin c (ascorbic acid) to a combination of anthocyanin and cyanidin in order to stabilize the antioxidant activities of anthocyanin and cyanidin. One of ordinary skill in the art would have had a reasonable expectation that vitamin c, being a strong antioxidant and also being know to stabilize phenolic compounds, would have been advantageous to add to a composition comprising the phenolics anthocyanin and cyanidin.

Applicant's arguments were fully considered, but not found persuasive.

Applicant argues that "there is no suggestion of the claimed mixture as acknowledged in the Office Action" (p. 7, Remarks). However, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each was well known in the art for treating inflammation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Thus, in the Instant case, although there is not a specific suggestion to combine a cyanidin and anthocyanin, the suggestion of such occurs naturally from the teachings

of the prior art which clearly disclose that cyanidin and anthocyanin inhibit inflammation respectively.

Applicant argues that "Lietti et al. discloses the anthocyanins as a source of cyanidin. The use for a food grade acid to prevent decomposition of the mixture could not have been deduced from Lietti et al., since the concern is the hydrolysis of the anthocyanin to cyanidin before administration" (p. 7, Remarks). The Examiner respectfully disagrees. The teachings of Lietti et al. are cited in order to relay that anthocyanins are known anti-inflammatory agents. It is not understood how Lietti et al. would be 'teaching away' from the addition of a food grade acid. Further, due to Applicant's amendments to the claims, the patent by Hellburg et al. is added into the obviousness rejection. It is clear that vitamin c was a known preservative for phenolic compounds. Vitamin C is well-known for its anti-oxidant properties. The ordinary artisan would have had a reasonable expectation that addition of vitamin c to a mixture of anthocyanin and cyanidin would have prolonged the shelf-life, and hence, activity of the mixture.

Claims 1, 3-6, 15-18, 27-30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gryglewski et al. (1987) in view of Lietti et al. (GB 1,589,294). in view of Hellburg et al. (US 5,691,360 A) in view of Brenner (US 5,462,932 A).

The teachings of Gryglewski et al., Lietti et al. and Hellburg et al. were discussed supra. None of the references specifically taught a carrier comprising dried cherry pulp.

Brenner (US 5,462,932 A) taught a medicinal compound, alendronate, in a syrup form for administration which comprised powdered cherries as a flavoring agent (see claims 1-15 and col. 5, 'Specific Formulation'). The formulation also included food grade acids to stabilize pH (see col. 3).

Thus, it was known that cherry powder was used in the art as a vehicle for medicinal compounds. Although Brenner did not specifically suggest the incorporation of cherry powder into a composition comprising isolated cyanidin and anthocyanin, it is deemed that because cherry powder (a form of dried cherries which would necessarily include the pulp thereof) was a known flavoring ingredient, that the addition of cherry powder to a medicinal composition would have been beneficial in formulating a medicinal dosage form which was pleasing to the palate. The ordinary artisan would have had a reasonable expectation that the addition of any known, convention carriers to a medicinal composition such as isolated cyanidin and anthocyanin would have provided for ease of delivery of the composition, as well as a means for suitably producing medicinal dosage forms of optimal efficacy. One of ordinary skill in the art would easily understand that medicinal compounds are rarely administered in their

pure form and are routinely mixed with carriers to provide specific concentrations of the active ingredient for pharmaceutical delivery.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

May 25, 2007